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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,016	12/29/2003	Vincent P. Bavaro	ACS 66062 (4045X)	6513

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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,016	Applicant(s) BAVARO ET AL.	
	Examiner Christopher P. Bruenjes	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30, 2007 has been entered.

WITHDRAWN REJECTIONS

2. The 35 U.S.C. 112, second paragraph rejection of claim 29 of record in the Office Action mailed April 27, 2007, Page 3 Paragraph 3, has been withdrawn due to Applicant's amendments and arguments in the Paper filed August 30, 2007.

Specification

3. The use of the trademarks PEBAX, PELLETHANE, HYTREL, SANTOPRENE, KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. For more information see MPEP 608.01(v).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 24-26, 28, 30, 32-37, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott (US 2003/0164063 A1).

Regarding claims 1-4, 25-26, 32-34, 36-37, the preamble “radiopaque marker” is given little patentable weight for two reasons. First, it appears the preamble is reciting purpose or intended use of the claimed article, which would only be given weight with regard to any structural difference the intended use results in. Second, if the preamble is not merely reciting purpose or intended use the only structural limitation provided by “radiopaque marker” is an article that is opaque to radiation, such as x-rays. This limitation would cover any article as long as it is opaque to radiation. The limitation that the marker is “for a medical device” is given little patentable weight because it is merely an intended use of the marker. Furthermore, the limitation that the marker “have a length, thickness, and cross-sectional size selected for attachment to the medical device . . . flexibility of the medical device” is given little patentable weight. Medical devices come in a myriad of different sizes including very small and very large objects. Therefore, to have a length, thickness, and cross-sectional size selected for attachment does not limit the marker to any particular size. Thus, the radiation shield taught by Elliott would have a size that would fall within the claimed limitation. The article of Elliott is a radiation-shielding

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article (p.3, paragraph 56) and therefore anticipates the structural limitations provided by the preamble. The article of Elliott comprises a polymer such as Pebax and radiopaque particles such as tungsten disposed within said polymer and a wetting agent for facilitating encapsulation of said particles such as a surfactant provided by a wax and a fluoropolymer and/or a coupling agent such as chemically modified polyethylene (p.5, paragraphs 88-93 and Table 2 on p.6). The tungsten has an average diameter of at least 2 microns and a maximum diameter of about 20 microns, as shown by the particle size distribution (p.6, paragraph 94). The radiopaque particles include greater 93.9 weight percent of the composite (Table 2 on page 6).

Regarding claims 24 and 35, the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94).

Regarding claims 28-30, 39, and 40, the limitations that the marker is a coating or attached to a medical device are intended use functional limitations of the radiopaque marker. The marker is an article and articles are defined by there structure not merely what the article is used for or how it is made. The functional limitations of these claims do not add further structural limitations to the marker, so they are given little patentable weight. The composite of Elliott has the ability to be used in the forms claimed, therefore the composite anticipates the claim. See MPEP 2114.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 5, 27, 31, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott (US 2003/0164063 A1).

Regarding claim 5, Elliott teaches all that is claimed in claim 1 as shown above, and teaches that the article is manufactured as a radiation shield. Elliott fails to teach that the article is necessarily formed to define a tubular structure. However, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that depending on the shape of the object the article of Elliott is providing a radiation shield to would determine the shape of the article of Elliott.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiation shield of Elliott to define a tubular structure when the object shielded from radiation has a tubular shape.

Regarding claims 27 and 38, Elliott teaches all that is claimed in claims 1 and 32 as shown above, but fail to teach that the article further comprises an antioxidant. However, it is well known in the art that antioxidants are added to elastomers in order to improve prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have

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been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the article of Elliott, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claim 31, although what the medical device is with regard to the marker is given little patentable weight because it is merely further defining an intended use of the claimed marker, this limitation adds at least some type of maximum size requirement to the size limitations in claim 1. Specifically, the marker in claim 31 is required to have a length, thickness, and cross-sectional size selected for attachment to a stent, guide wire, balloon, or embolic filter, which are all relatively small articles. However, there is still no specific size requirement and Elliott teaches many different types of articles having different sizes, so it would be obvious to one having ordinary skill in the art at the time Applicant's invention was made the article of Elliott would be formed with the length, thickness, and cross-sectional size desired for the intended end result of the desired article produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the length, thickness, and cross-sectional size that would be sufficient for attachment to a stent, guide wire, balloon, or embolic filter, depending on the intended end result of the article, since Elliott teaches many different sized articles.

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9. Claims 1 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al (USPN 5,776,141) in view of Elliott (US 2003/0164063).

Regarding claims 1-4 and 32-34, Klein et al teach a radiopaque marker for a medical device having a length, thickness, and a cross-sectional size selected for attachment to the medical device for providing radiopacity without substantially affecting the flexibility of the medical device comprising a polymer and radiopaque particles (col.11, l.15-30). The polymer is a polyether block amide copolymer and said radiopaque particles comprise tungsten powder, which is loaded approximately 36 volume percent of said marker since it is 90% by weight (col.11, l.22-26). The blend of the polymer and the radiopaque particles forms a highly radiopaque yet relatively flexible radiopaque marker configured for securing to the intraluminal medical device and the radiopaque particles (col.11, l.15-30). The marker is formed with a minority of the volume metal solids and the majority of volume nonmetal.

Klein et al fail to teach adding a wetting agent for facilitating encapsulation of said particle by said polymer and the diameter of the particles. However, Elliott teaches that to improve the packing density of tungsten powder the powder is milled to deagglomerate the fine particle clusters. To get higher packing densities such as 36 volume percent and approximately 91.3 weight percent, Elliott teaches the mean particle size is between 1 and 10 microns (p.2, paragraph 43). Elliott further teaches specific examples wherein when the median particle diameter is about 10 microns, the 90% of the particles have a diameter less than 18.5 microns (p.6, paragraph 94). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that when the mean particle size is within the range of 1 and 10 microns the maximum diameter of substantially all particles would be about 20

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microns. Furthermore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that when 90% of the particles have a diameter less than 18.5 microns very few if any of the particles have a diameter greater than 20 microns. Also, one of ordinary skill in the art would have expected absent any teaching to the contrary that a statistically insignificant amount of particles having a diameter greater than 20 microns would not render the article different, besides the fact that the claim specifies "about" 20 microns which would include some diameters greater than 20 microns.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the radiopaque particles of Klein et al with a mean diameter of at least 2 microns and a maximum diameter of about 20 microns in order to maximize the packing density and ultimately be able to form a combination with 36 volume percent and approximately 91.3 weight percent radiopaque particles, as taught by Elliott.

Furthermore, Elliott teaches that a wetting agent such as maleic anhydride graft polyolefin is blended with the polymer forming the radiopaque particle containing article as a strength enhancing agent (p.5, paragraph 92). Therefore, it would have been obvious to one having ordinary skill in the art to add maleic anhydride graft polyolefin to a tungsten and polymer mixture in order to enhance the strength of the mixture, as taught by Elliott.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add a maleic anhydride graft polyolefin to the radiopaque marker of Klein et al in order to enhance the strength of the mixture, as taught by Elliott.

Regarding claim 5, Klein et al teach the marker has a ring shape with is a tubular structure.

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Regarding claims 24 and 35, Elliott teaches the radiopaque particles are substantially equiaxed as shown by the particle size distribution (p.6, paragraph 94).

Regarding claims 25-26 and 36-37, Elliott teaches the wetting agent for facilitating encapsulation of said particles is a surfactant provided by a wax and a fluoropolymer and/or a coupling agent such as chemically modified polyethylene (p.5, paragraphs 88-93 and Table 2 on p.6).

Regarding claims 27 and 38, it is well known in the art that antioxidants are added to elastomers in order to prevent oxidative decomposing, and therefore have longer stability and life. Therefore, it would have been obvious to one having ordinary skill in the art to add an antioxidant to an article formed of Pebax in order to increase the stability and life of the article, since antioxidants prevent oxidation and decomposition caused by oxidation. Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to add an antioxidant to the marker of Klein et al, since it is well known in the art as a common additive to elastomers and would be added in order to prevent premature oxidation of the article.

Regarding claims 28-31, 39, and 40, the limitations that the marker is a coating or attached to a medical device are intended use functional limitations of the radiopaque marker. The marker is an article and articles are defined by their structure not merely what the article is used for or how it is made. The functional limitations of these claims do not add further structural limitations to the marker, so they are given little patentable weight. Furthermore, Klein et al teach the marker is attached to a medical device such as a stent, balloon, or guide wire. Whether the marker is attached by extrusion coating is given little patentable weight

absent the showing that attachment by that particular method provides an unobvious structure over the attachment of Klein et al.

Response to Arguments

10. Applicant's arguments regarding the 35 U.S.C. 112, second paragraph rejection of claim 29 has been considered but they are moot since the rejection has been withdrawn.

11. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 1-4, 24-26, 28, 30, 32-37, 39, and 40 over Elliott have been fully considered but they are not persuasive.

In response to Applicant's argument that Elliott fails to teach that the article has the length, thickness, and cross-sectional size claimed, the claimed length, thickness, and cross-sectional size includes almost every length, thickness and cross-sectional size selected for providing radiopacity without effecting the flexibility of a medical device to which it is attached. The claim only requires that the size be selected for attachment to a medical device. Medical devices come in a vast range of sizes that would include articles large enough for any of the articles taught by Elliott to be the correct size to attach. Furthermore, beyond the size limitation itself the rest of the added limitations only add intended use or functional limitations to the marker, which are only given weight insofar as the structure required having the capability to perform the functions. None of the added functional limitations require any additional structure beyond what is already claimed in claims 1 and 32. The composite of Elliott is formed of similar materials to the claimed invention and made in any number of different sizes. Therefore, Elliott

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anticipates a marker having a size that would not affect the flexibility of a medical device to which it is attached.

In response to Applicant's argument that Elliott fails to teach that the composite could be used to increase the radiopacity of another device, the composite of Elliott anticipates the claimed limitations and therefore whether Elliott would envision the use of the claimed invention is not germane.

In response to Applicant's argument that using the limitation "having a length, thickness and cross-sectional size selected for attachment to a medical device" provides structure to the claim. The broadest reasonable interpretation of the limitation merely requires a marker that has a length, thickness and cross-sectional size that would allow it to be attached to a medical device without substantially affected the flexibility of the medical device. The limitation does not require that the marker actually be attached to a medical device. By teaching a myriad of different sizes Elliott anticipates at least in one embodiment a size that fits the claimed size requirement.

In response to Applicant's argument that the limitation that the marker is formed of a coating or an extrusion coating is not functional language and is structural, only the marker is claimed and attaching the marker to a medical device is an intended use/functional limitation, because the medical device is not part of the claimed marker. The medical device is merely a device intended to have the marker attached to it, however, the medical device is not being claimed. Therefore, the marker standing alone, separate from the medical device being formed by either casting or coating would form the same structural article. Whether there is a structural

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difference in the medical device by having a marker coated onto the device or formed and attached subsequently is not relevant to the patentability of the marker itself.

12. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 5, 27, 31, and 38 over Elliott have been fully considered but they are not persuasive.

In response to Applicant's argument that it is unobvious for the composite of Elliott to have a tubular shape, only the marker is being claimed not the medical device. It is not relevant to the obviousness of the tubular shape of the composite of Elliott whether Elliott teaches using the composite as a marker on a medical device. As long as it would be obvious for the composite of Elliott to be formed into a tubular shape, the composite teaches the claimed invention. In this case, it would be obvious for a radiation shield of Elliott to have a tubular shape when the radiation shield is being used around a tubular object.

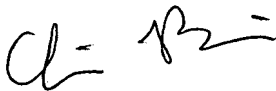
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Christopher P Bruenjes
Examiner
Art Unit 1794

CPB
October 15, 2007